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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,422	11/13/2003	Mahmoud M. Abdel-Monem	P05844US01	9957

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EXAMINER	
OH, TAYLOR V	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,422	ABDEL-MONEM ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1-2 are pending.

Claims 1-2 have been rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claim 1 under 35 U.S.C. 112, second paragraph has been maintained due to applicants' failure to modify the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1-2 under 35 U.S.C. 112, first paragraph, due to applicants' failure to modify the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of Claims 1-2 under 35 U.S.C. 102(a) as being anticipated clearly Kirschner et al (U.S. 6,352,713) has been maintained for the reasons of the record on 7/1/05.

2. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated clearly Henry , Jr. et al (US 6,358,544) has been maintained for the reasons of the record on 7/1/05.

3. The rejection of Claims 1-2 under 35 U.S.C. 102(b) as being anticipated clearly Nikiforov et al (N.E. Baumana (1971), 108, p. 182-4) has been withdrawn.

4. The rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated clearly Godfrey (US 4,684,528) has been withdrawn.

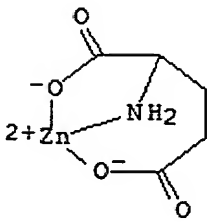
5. The rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated clearly Kaczmarczyk et al (Verhandlungen der Deutschen Gesellschaft fuer Innere Medizin, 1974, 80 , p.1274-1277) has been withdrawn.

Newly Applied Rejection

Because applicants have newly revised claim 1 in the amendment, another prior art rejection is applied.

6. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Weitzel et al (Hoppe-seyler's Zeitschrift fuer Physiologische chemie ,1953, 292, p. 286-302).

Weitzel et al discloses a 1:1 complex of zinc glutamate compound to be used in the effect of zinc compounds on blood sugar on dog(see abstract page) as shown below:



. This is identical with the claims.

Applicants' Argument

I. Applicants argue the following issues:

a. The Kirschner does not describe the claimed preparation or properties and the exact nature of ferrous glutamate is unspecified by the Kirschner; the ferrous glutamate is not a preferred source of iron among many different types of commercially available sources of iron; furthermore, a substance containing iron

in the ferrous state and glutamic acid could be one of three different chemical entities, or a mixture of two or all three;

b. Just like the Kirschner, Henry does not provide any information on the exact nature of zinc aspartate; furthermore, zinc gluconate is exemplified , but which contains one zinc for every 2 molecules of the gluconate anions and this is not neutral unlike the claimed complex;

c. The Nikiforov and Kaczmarczyk et al do not teach the steps of claim 1; therefore, it can not be obvious;

d. The Godfrey does not teach the claimed complex ;instead, it teaches $Zn(aminoacid)_2$, which is different from the claimed invention;

e. Moore is to prepare amino acid transition metal chelates, by using preferably 1.8 and 2.5 molecules of amino acid for its purpose, but not a 1:1 neutral complex which was only discovered after a multi-step process to synthesize the claimed complex;

e. ICN does not provide guidance as to chemical , physical, or nutritional properties; the instant invention requires more than looking the words "synthetic amino acid" from the ICN prior art since the claimed 1:1 neutral complex was discovered only after a multi-step process to synthesize the claimed complex.

The applicants' argument have been noted, but these arguments are not persuasive.

First, with respect to the first argument, the Examiner has noted applicants' argument. However, applicants have admitted the possibility that Kirschner's ferrous glutamate can be a mixture of two, which is the same as the claimed 1:1 neutral complex of the iron and glutamic acid. Therefore, Kirschner's ferrous glutamate complex does inherently have the claimed complex with the specific ratio. Therefore, applicants' argument is irrelevant to the issue of the claimed invention.

Second, with respect to the second argument, the Examiner has noted applicants' argument. However, applicants have admitted the possibility that Henry 's zinc aspartate can be a mixture of two, which is the same as the claimed 1:1 neutral complex of the zinc and aspartic acid. Therefore, just the case of Kirschner's ferrous glutamate complex, Henry 's zinc aspartate does inherently have the claimed complex with the specific ratio. Therefore, applicants' argument is irrelevant to the issue of the claimed invention.

Third, with respect to the third and fourth arguments, the Examiner has agreed.

Fourth, with respect to the fifth argument, the Examiner has noted applicants' argument. However, the Moore reference does offer the following guidance for how to prepare amino acid transition metal chelates in the 1:1 neutral complex between them (see col. 3 ,lines 17-25):

> To effectively form the chelate, it is necessary to neutralize the aqueous sodium or potassium salts of the amino acids and fatty acids to a pH between 3 and 7. Then, the water soluble salts of transition metals may be reacted with the neutralized sodium or potassium salts of amino acids and fatty acids to provide between 1 and 3, and preferably between 1.8 and 2.5 molecules of amino acid per transition metal, thereby forming an aqueous mixture of amino acid transition metal chelates and fatty acids.

From this teaching, it is possible for the skilled artisan in the art to prepare the 1:1 neutral complex of the Fe element (see col. 4 , line 57) and the glutamic acid (see col. 8 ,line 33) because Moore expressly teaches the broad workable range of from 1 to 3 molecules of amino acid per transition metal. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to change from the prior art ratio to the claimed ratio by routine experimentation depending upon the weight of the animal by routine experimentation. This is because such a modification to be successful and feasible as the guidance (see col. 3 ,lines 17-25) shown in the prior art. Therefore, applicants' argument is irrelevant to the issue of the claimed invention.

Fifth, with respect to the sixth argument, the Examiner has noted applicants' argument. However, the reference does offer the guidance that the synthetic amino diet composition can be adjusted depending on its use(see page 1194, right column). Furthermore, it is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality . In re Becker, 33 USPQ 33 (C.C.P.A. 1937). In re Russell, 439 F. 2d 1228, 169 USPQ 426 (C.C.P.A.). Therefore, it would have been obvious to the skilled artisan in the art to

be motivated to change from the prior art ratio to the claimed ratio depending upon the use of the amino acid diet for any particular animal. This is because such a modification to be successful and feasible as the guidance (see page 1194, right column) shown in the prior art. Therefore, applicants' argument is irrelevant to the issue of the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*** 12/20/05

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